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Genetic Privacy, Discrimination and Research in Washington State: Findings, Conclusions and Recommendations of the Washington State Board of Health Genetics Task Force

Conclusions and Recommendations

The following conclusions and recommendations reflect the opinions of Task Force members and are based upon the Task Force's findings described previously. Each section below presents the conclusions and recommendations proposed by a subcommittee representing a specific use of genetic information. In most cases, the Task Force adopted the conclusions and recommendations brought forth by each subcommittee via consensus; on issues where consensus was not achieved minority opinions are stated.

Conclusions and Recommendations Regarding the Use of Genetic Information in Health Care: a) The diagnosis of symptomatic patients; b) Reproductive decision-making; and c) Predictive genetic testing for low penetrant genetic disorders

Incidence of discriminatory actions based upon genetic information

Subcommittee One found no evidence of discrimination based on genetic testing for individuals with symptomatic disorders and concluded that the technology is appropriate for medical diagnostic purposes. Furthermore, the Subcommittee concluded that there is no need for legislation to expand protection of personal privacy in the area of prenatal genetic testing. However, Subcommittee One concluded that predictive genetic testing may place individuals at risk for genetic discrimination should such information exceed the bounds of the medical care system. For example, a woman identified in a family with an abnormality of a BRCA1 gene could theoretically be discriminated against in obtaining health insurance or employment because of the perceived increased fiduciary risk she would present to an employer or in social stigmatization. Similarly, an individual identified at age 20 as carrying the gene for Huntington

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disease could be discriminated against in employment, obtaining health insurance, or from individual or group life insurance.

Strategies to safeguard civil rights and privacy related to genetic information

With respect to strategies to safeguard civil rights and privacy related to genetic information, Subcommittee One concluded that information obtained by genetic testing for symptomatic conditions should become part of the medical record, similar to other testing that would be performed for medical diagnosis. The Subcommittee also concluded that the risk of inappropriate use of the genetic information is the same as for other medical testing performed voluntarily for individuals and there is no necessity to expand this protection.

Recommendations: Subcommittee One had one recommendation regarding strategies to safeguard civil rights and privacy related to predictive genetic information. The members recommended that reports of predictive genetic testing should remain in medical records and receive the same protection as other sensitive medical information. Hospital policy, Washington state statute, and HIPAA regulations protect medical information.

Remedies to compensate individuals for inappropriate use of genetic information

The members of Subcommittee One concluded that the current legal tort system provides sufficient remedies if diagnostic or reproductive genetic information is misused in a health care setting or by a health care provider and no additional remedies are necessary for these categories of genetic testing.

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Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Subcommittee One reached the following conclusion regarding incentives for further research and development on the use of DNA to promote public health, safety and welfare. First, the members concluded that as genetic technologies improve through research, genetic testing will be introduced into the public health system as an adjunct to newborn screening for treatable genetic diseases. This will promote and assist the safety and welfare of young children detected with treatable disorders. The Subcommittee supported the use of genetic testing for this purpose.

Second, the Subcommittee concluded there is no need for legislation to protect individual privacy in the area of reproductive health. Adequate safeguards exist within the research community (IRBs), Washington State law, and HIPAA regulations.

Lastly, Subcommittee One concluded that development of testing for risk factors associated with multifactorial common diseases such as diabetes, hypertension, renal disease, and cardiovascular disorders will have a beneficial effect on public health policy and the welfare and safety of the population and therefore this research should be encouraged as a means of improving the health of the population.

Additional Comments

In view of the expanding use of genetic testing for the detection of genetic disorders and the prediction of future disease, there is a need for genetic counseling to assist physicians and individuals with selection of tests and interpretation of results. Washington State has no academic program to train genetic counselors. Subcommittee One recommended that serious

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attention be given to establishing a graduate program in genetic counseling at the University of Washington to address the current and future needs of the State's population.

Conclusions and Recommendations Regarding State Mandated DNA Collection/Testing: the Newborn Screening Program and the Criminal DNA Database

Incidence of discriminatory actions based upon genetic information

Subcommittee Two concluded that there is no evidence of discrimination under the Newborn Screening Program or the criminal DNA database system in Washington State.

Recommendations: The majority of Subcommittee Two had no recommendations for the Legislature in regard to discrimination and either of these State programs. Professor Philip Bereano recommended that the tissue samples in the forensic database be destroyed after DNA profiling to prevent privacy violations and discrimination.

Strategies to safeguard civil rights and privacy related to genetic information

Concerning strategies to safeguard civil rights and privacy, the majority of Subcommittee Two concluded that protections currently in place for the Newborn Screening Program and the criminal DNA database appear to be adequate to protect civil rights and privacy. Professor Bereano dissented from this conclusion.

Recommendations: The majority of the Subcommittee had no recommendations related to privacy and civil rights policies associated with the NBS program and the criminal DNA database.

Professor Bereano reiterated his recommendation for the creation of a policy that requires destroying specimens collected from convicted criminals after they are tested and the DNA code has been entered in the criminal DNA database.

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Remedies to compensate individuals for inappropriate use of genetic information

After reviewing both the Uniform Health Care Information Act and the Release of Records for Research statutes, members of Subcommittee Two concluded that these statutes provide remedies for the inappropriate use of genetic information collected and stored under the NBS program. With respect to genetic information that is collected and maintained for the criminal DNA database, the Subcommittee concluded that federal law provides penalties for inappropriate use, but neither federal nor state law provide specific remedies to individuals beyond the current tort system.

Recommendations: The Subcommittee had no recommendations regarding these policies.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

With respect to incentives for further research and development using NBS specimens and data, this Subcommittee reached the conclusion that protections provided by DOH policy, DSHS/DOH Human Subject Research Review Board policy, and the Release of Records for Research statute appear to be adequate to protect individuals without unnecessarily impeding research to promote public health safety and welfare.

Recommendations: The Subcommittee had no recommendations with respect to research and the Newborn Screening Program. Furthermore, given the limited nature of the data provided by testing conducted for the criminal DNA database, members concluded that incentives for research using this resource are not warranted.

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Additional statement

The members of this Subcommittee cautioned that any infringement on an individual's rights to free choice regarding their DNA/genetic information is perilous and to be avoided in all but the most specific and compelling circumstances found in the newborn screening and criminal DNA database systems.

Conclusions and Recommendations Regarding the Use of Genetic Information in Research

Incidence of discriminatory actions based upon genetic information

The incidence and risk of discriminatory actions based upon genetic information from research activities led Subcommittee Three to the following conclusions.

First, Chapter 49.60 RCW and Chapter 70.02 RCW provide substantive legal protection against discrimination based on genetic information regardless of the source. However, gaps in protection exist that may leave research subjects vulnerable to the misuse of genetic information obtained in research, if that information would have to be reported by the subject to insurers, employers, or others who may make decisions on the basis of that information and use it in an adverse fashion against the individual.

Second, State law (WAC 284.43.720) prohibits health insurers from requesting or making a decision about insurability based on predictive test results in the absence of a current diagnosis made by clinical examination. This is true whether the information is derived as part of clinical testing or from research studies.

Third, existing legislation does not address the type of genetic information an insurance company or employer may request and expect to receive from an individual or limit subsequent

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disclosure, unless this information is considered as “health care information” in the context of Chapter 49.60 RCW and Chapter 70.02 RCW.

The Subcommittee’s final conclusion in this regard was that there are no external mechanisms to monitor compliance with the ADA or Chapter 49.60 RCW, which leaves subjects or witnesses who feel genetic information may have been used in an adverse fashion responsible for reporting violations.

Recommendations: Subcommittee Three recommended that the Legislature authorize the funding of efforts by the DOH to educate consumers, research subjects, researchers, health care providers, employers, and insurers about how genetic information derived from DNA sequence, as part of medical information, can be used, the concepts and consequences of anonymity in research, and the reporting and other mechanisms available to those who believe they have been discriminated against.

Professor Bereano recommended that the Legislature adopt policies to outlaw genetic discrimination and protect genetic privacy, which would bolster peoples’ confidence in the health care system, assuring that they have no hesitations about getting the diagnoses and treatments they may need.

Strategies to safeguard civil rights and privacy related to genetic information

After considering numerous strategies to safeguard civil rights and privacy related to genetic information that is created or used in the course of research, the majority of Subcommittee Three concluded that existing federal and state laws provide substantial protection with respect to the privacy and civil rights of research subjects and that knowledge of existing laws that protect privacy and civil rights may encourage people to participate in genetic research.

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The Subcommittee also concluded that waivers of consent for research on previously obtained tissues or samples are appropriate for some types of research under current federal regulations. The Subcommittee's final conclusion in this area was that appropriate monitoring and/or oversight systems are lacking for research on human subjects in some settings.

Recommendations: Subcommittee Three proposed four recommendations regarding strategies to safeguard civil rights and privacy with respect to genetic information that is used or created in the course of research. The Subcommittee recommended that research involving human subjects in the State of Washington be subject to the standards that are in place for federally funded human subjects research. The Subcommittee's second recommendation was that subjects, health care providers, insurers, and employers have access to all existing laws (?) that protect the privacy of medical information, including DNA-based information. Third, the majority of the Subcommittee recommended that State policies leave the responsibility of monitoring research activities that involve human subjects to IRBs; Professor Bereano dissented from this recommendation. Professor Bereano expressed a fourth recommendation as a minority opinion. He recommended that the Legislature of the State of Washington propose and enact legislation that explicitly defines genetic discrimination, genetic information, and privacy rights of individuals with respect to genetic information.

Remedies to compensate individuals for inappropriate use of genetic information

The majority of Subcommittee Three concluded that existing penalties for the violation of laws protecting the privacy and civil rights of individuals who provide genetic information for research purposes are adequate. However, Professor Bereano concluded that these laws are inadequate.

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Recommendations: In line with the majority's conclusion, the Subcommittee recommended no further action by the State. Professor Bereano recommended that, as has been done in many other states, Washington pass legislation that protects the privacy of genetic information, defines and outlaws genetic discrimination, and provides avenues for redress when violations are proven.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Concerning the use of genetic information in research and the Task Force's findings related to incentives for further research and development on the use of DNA to promote public health, safety and welfare, the members of Subcommittee Three drew the following conclusions. At present, the development of genetic tests far outpaces the availability of information and personnel to interpret and apply the test results in a health care setting. Research studies that use identifiable DNA samples or anonymous DNA samples are among the types of biomedical research that are important for the advancement of medical and public health knowledge and may provide benefits to the citizens of Washington. The Subcommittee noted, however, that the costs for making genetic testing available, as a result of costly research and development studies, may impede equitable availability of such resources to all segments of the population. Overall, the Subcommittee agreed that academic and private researchers receive adequate incentives to conduct genetic research.

Recommendations: Subcommittee Three recommended that in all research involving genetic information from individuals, explicit voluntary consent or assent should be obtained, as detailed in current applicable law and regulations.

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Conclusions and Recommendations Regarding the Use of Genetic Information for Other Social Purposes Such as Health, Life, and Disability Insurance and Employment

The incidence of discriminatory actions based upon genetic information

The members of Subcommittee Four came to the following conclusions regarding the incidence of discriminatory actions based upon the use of genetic information for social purposes such as health, life, and disability insurance and employment.

Evidence of discrimination based upon genetic information presented to the Task Force by DOH GSS does not suggest widespread problems regarding the use of genetic information for social purposes such as health, life, or disability insurance, or employment. However, the incidents reported to the DOH GSS may not represent all such events. Subcommittee Four recognized that quantitative data on the extent of actual or perceived discrimination based on genetic information might be lacking.

The majority of Subcommittee Four concluded that existing regulatory policies and practices provide some protections against discrimination based on genetic information; in particular, state and federal laws protecting the privacy of health information and limiting the use of health information by employers and insurers provide important protections. However, a minority opinion stated by Mr. Ty Thorsen suggests that gaps exist in the protection provided by these existing laws. Mr. Thorsen disagreed with the majority conclusion because neither the ADA nor Chapter 49.60 RCW explicitly mentions genetic information and the interpretation that these laws cover genetic information has not been tested. One member of the general Task Force, Professor Bereano, concurred with Mr. Thorsen's conclusions.

Recommendations: The majority of the Subcommittee did not identify any areas in which additional legislation was deemed necessary for the protection of individuals against discrimination based on the use of genetic information in insurance or employment settings.

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Mr. Thorsen, in a dissenting opinion supported by Professor Bereano, recommended that Washington State should change Chapter 49.60 RCW to explicitly include “genetic information” in the list of characteristics that receive protection under the law. As it is written, the law only explicitly prohibits discrimination based on “sex, race, creed, color, national origin, marital status, age or the presence of any sensory, mental or physical disability, or the use of a trained dog guide or service animal by a disabled person.”

Strategies to safeguard civil rights and privacy related to genetic information

Subcommittee Four reached the following conclusions regarding strategies to safeguard civil rights and privacy related to genetic information in the context of health, life, and disability insurance and employment.

Existing laws and regulations are sufficient to protect the privacy of individuals in regard to genetic information that is included in the medical record or obtained as a part of health care. Furthermore, existing state and federal laws as well as industry practices/policies, provide protection for an individual’s privacy and civil liberties with respect to health, life, and disability insurance and existing laws provide protection against employment discrimination or other privacy/civil rights violations.

Two members of this subcommittee, Mr. Ty Thorsen and Dr. Wylie Burke, and three members of the general Task Force, Ms. Robin Bennett, Professor Philip Bereano and Dr. Peter Byers, concluded that restriction of marriage between cousins can be construed as genetic discrimination. There is little biological basis for such restrictions (insert reference: Bennett et al., *Journal of Genetic Counseling*, 2002;11:97-119) and it is legal to marry a first cousin in many other states. The Washington State law prohibiting marriage of first cousins (Chapter 26.04.020 RCW) may not be justified on a scientific basis.

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Recommendations: The majority of the Subcommittee did not identify any areas of law in which additional legislation is needed to protect the privacy of individuals with regard to the use/disclosure of genetic information.

Dr. Wylie Burke recommended revising the Uniform Health Information Act to ensure that genetic information obtained in the course of research participation is included in the definition of medical information; Mr. Thorsen and Dr. Julie Sanford-Hanna joined Dr. Burke in this recommendation.

Two members of the Subcommittee, joined by three members of the general Task Force, recommended that the Legislature revise Chapter 26.04 RCW to remove the ban on first cousin marriage.

Remedies to compensate individuals for inappropriate use of genetic information

Members of this Subcommittee concluded that the existing tort system provides an avenue to compensate individuals for inappropriate use of genetic information.

Recommendations: Subcommittee Four did not identify any additional action required by the State.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

After considering the Task Force's findings regarding incentives for further research and development, Subcommittee Four concluded that Washington law must be such that biotechnology companies and other researchers want to locate or continue to remain and operate within the state. Furthermore, policies are needed to address the perception of the risk of discrimination associated with participating in a genetic research study.

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Recommendations: Subcommittee Four joined with the members of Subcommittee Three and recommended that the State implement programs or other processes to educate the public, researchers, employers, and health care providers about existing measures to protect an individual's civil liberties and right to privacy. Such a program may reduce the perception that the risk of discrimination is high and encourage people to participate in genetic research. The Subcommittee advised that any process to create policies addressing the use of genetic information in research should invite participation from all stakeholders.